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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,871	01/24/2002	James D. Thacker	38599.0012	5347
25227	7590	11/16/2004	EXAMINER	
MORRISON & FOERSTER LLP 1650 TYSONS BOULEVARD SUITE 300 MCLEAN, VA 22102			HINES, JANA A	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,871	THACKER, JAMES D.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment filed August 23, 2004 has been entered. The examiner acknowledges the amendment to the specification. Claims 1,13, 41 and 42 have been amended. Claims 1-44 are under consideration in this application.

Response to Arguments

2. Applicant's arguments filed August 23, 2004 have been fully considered but they are not persuasive. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 1-25 and 36-39 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. Applicant asserts that the amendments overcome the rejections. However it is the examiner's position that the amendments do not overcome all the rejections for the reasons stated below.

4. Claim 1 is still unclear. Now claim 1 recites "...adding a primary antibody, which is specific to said marker, to the digested bacteria and thereby contact released marker;..." The claim is indefinite because it is unclear whether the claim is stating that the primary antibody is specific for the marker and specific to the digested bacteria. Although applicant asserts that the antibody is added to the bacteria, the claim language confers a different interpretation. Thus suggested claim language would be

adding to the sample comprising the digested bacteria and released marker, a primary antibody that binds said marker. It is unclear what applicant intends with respect to the "thereby contact released marker" language. Is applicant stating that the primary antibody will bind only released marker? It is also unclear whether there is a difference between "said marker" and "released marker". If the markers are one in the same, then consistent terminology should be used. If there are two types of markers, then applicant should clarify. Thus clarification is required.

The recitation of "...adding a second antibody, which is specific for said primary antibody and conjugated to a reporter molecule, to the digested bacteria and thereby contact primary antibody;..." is unclear. It is unclear if applicants' statement is drawn to adding to the sample a second antibody conjugated with a reporter molecule, wherein the second antibody binds to the primary antibody or if applicant intends something else. Thus contrary to applicant's belief that the rejections are now moot, the rejection is maintained because the claim language is confusing. Claim 13 has a similar problem, therefore the above comments also apply to claim 13.

5. It is unclear how the determination of the type of bacteria can occur as recited in claims 1 and 13. Applicant asserts that pages 8-9 teach typing of bacteria, however those pages only refer to maintaining the viability of an antibody once it is immobilized on a solid surface. Page 10 of the instant specification defines typing as the identification of a bacterial genus, species, or serotype. The use of a generic capture antibody in claim 1 would not allow one of skill in the art to determine the genus,

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species or serotype of the captured bacteria. Thus the goal of the preamble of the claim is not achieved.

It is noted that claim 13 only uses antibodies specific for the marker. There is no use of an antibody that binds to a particular type of bacteria. Therefore it would be impossible to determine the type of bacteria without such. Thus, applicant's arguments are not persuasive. The claims fail to recite the use of multiple antibodies specific for different types of microorganisms, thus it is unclear how the microorganisms can be typed. It is unclear how one could determine what type of microorganism is present in the sample unless one already knew what microorganisms were in the sample and what antibodies to use to detect such microorganisms. Therefore, the claims are still unclear and the metes and bounds cannot be ascertained. Clarification is required since applicant's assertions are not persuasive.

6. Claim 42 recites the limitation "said detectable reporter molecule" and is therefore still rejected. There is insufficient antecedent basis for this limitation in the claim.

7. The new matter rejection of claims 1-44 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record. The rejection was on the grounds that applicant failed to specifically point to support for the identity of an immobilized capture antibody specific to one or more types of bacteria as recited by the newly amended claims.

Applicant asserts that pages 8-9 teach that primary antibodies of any available specificity can be used. However pages 8-9 of the instant specification are drawn to maintaining the viability of antibodies within a kit. Moreover, the primary antibodies are specific for the marker and do not provide support for applicant's new matter. The primary antibodies are not specific to different types of bacteria and do not aide in the ability to type the bacteria. Thus applicants' statements are not persuasive. Moreover, all the claims do not require the use of capture antibodies that are necessary to allow the bacteria to be typed. Thus applicants' arguments are not persuasive.

Neither the specification nor originally presented claims provides support for immobilizing a capture antibody specific to one or more types of bacteria on a solid support. Applicant still did not point to support in the specification for immobilizing a capture antibody specific to one or more types of bacteria on a solid support that would allow one of skill in the art to type the bacteria. Thus, there appears to be no teaching of an immobilized capture antibody specific to one or more types of bacteria and allow for the typing of that bacteria. Applicant claims that there is support in instant specification and claims for support of the amendment which are drawn to an immobilized capture antibody specific to one or more types of bacteria, however it appears that the entire specification appears to fail to recite support for the newly recited immobilized capture antibody specific to one or more types of bacteria. Rather the specification refers to methods useful for the detection of a single or mixed species of microorganisms using antibody specific to the marker, not to specifically typing the bacteria. Applicant's assertion that any antibody including unknown antibodies could be

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used within the method has no support. Moreover, the kit claims do not even require the use of a capture antibody that would allow typing of the bacteria to occur. Therefore, it appears that there is no support in the specification. Therefore, the claims incorporate new matter and the rejection is maintained.

8. The written description rejection of claims 8, 25 and 29 under 35 U.S.C. 112, first paragraph. The rejection was on the grounds that the written description in this case only sets forth the specific reporters separately. There is no written description of combinations of reporters; therefore the written description is not commensurate in scope with the claims drawn to combinations thereof.

Applicants' simply assert that combinations of reporter molecules are well known in the art without any scientific support. However, the issue is that the instant specification fails to disclose the combinations. Neither the specification nor the claims disclose how to use a combination of reporters in a single assay or kit. Neither the claims nor the specification disclose how to use a combination of reporter molecules in the claimed method or kit. There is no disclosure as to what combinations of reporter molecules can be used together and which ones cannot be used in the assay or kit. The specification does not disclose structural examples of a combination of reporter molecules. Thus, applicant's statements to the contrary are not persuasive and the rejection is maintained in view of the lack of evidence that applicant was in possession of a combination of reporter molecules.

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9. The rejection of claims 1-44 under 35 U.S.C. 102(b) as being anticipated by Thacker (WO 99/12015). The rejection was on the grounds that Thacker teaches a method for typing or enumerating bacteria in a sample comprising: immobilizing capture antibody; contacting the sample with the immobilized antibody; allowing the production of the marker; digesting the marker; adding primary and secondary antibody; detecting the reporter molecule and determining the type or quantity of the bacteria in the sample just as instantly claimed. Thacker also teaches kits with various components such as solid supports, chemical biomarkers such as tetrazolium salts, capture antibodies, both primary and secondary antibodies, and detectable labels. Therefore, Thacker teaches kits for the detection or enumeration of one or more types of bacteria comprising the same components such as a soluble substrate (tetrazolium), primary antibodies specific for the marker; secondary antibodies, detectable reporter molecules, wash, dilution and digestions buffers, nutrient media just as recited by the instant claims.

Applicants assert that because the specification was amended and an unexecuted declaration was submitted, drawn to giving the instant case priority to 09/148,491 and 60/057,657, the rejection should be withdrawn. However, the rejection will be maintained for the following reason.

The application is a utility application filed under 35 U.S.C. 111(a) on or after November 29, 2000, therefore the specific reference to prior applications must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. This time period is not extendable and a failure to submit the reference

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required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). Applicant failed to timely submit specific reference to the prior applications. In view of applicants' failure to timely the pendency claim, applicant has waived any benefit to prior applications. Thus applicant's argument is not persuasive and the rejection is maintained.

Oath/Declaration

10. This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. The supplemental oath or declaration is unexecuted as required under 37 CFR 1.67. See MPEP §§ 602.01 and 602.02.

Specification

11. The amendment filed August 23, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicants have amended the specification to now claim priority to applications 09/148,491 and 60/057,657. However this claim for priority has not been accepted for the reasons stated above. Applicant is required to cancel the new matter in the reply to this Office Action.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
November 9, 2004


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